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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,937	05/28/2002	Brent C. Gerberding	S63.2-10447	2387
490	7590	11/14/2007		
VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER HOUSTON, ELIZABETH	
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			11/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/063,937

Applicant(s)

GERBERDING, BRENT C.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,13-18,22-28,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 and 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,13-15,26-28,34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (USPN 6,652,579) in view of Garrison (USPN 6,520,984) and further in view of Erbel (US 2004/0116998).**

3. Cox clearly teaches a stent having a longitudinal axis, comprising a plurality of serpentine bands formed of interconnected struts (Figs. 6) including: special struts (54), which extend between peaks and troughs having a first side with a first region of first curvature relative to the longitudinal axis and a second side with a second region of second curvature relative to the longitudinal axis, the first region opposite the second region and having a radiopaque marker (Col. 3, line 14) between the two regions. Each special strut has a plurality of interconnected struts adjacent the first side and a plurality of interconnected struts adjacent the second side, each having curved regions that curve about marker. The first serpentine band is connected to the second serpentine band by a connector (52), which extends from the distal end of the first serpentine band to the proximal end of the second serpentine band.

4. The special struts are located between the ends of the stent. Some of the special struts (54b or 54c) are located anywhere between the middle of the stent and halfway

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from the middle to the end of the stent. In other embodiments disclosed by Cox (Figs. 11-15), there is a plurality of radiopaque markers and special struts at the end of the stent. Regarding claims 26 and 27 requiring that the special struts be located only in the intermediate serpentine bands or not at the end of the stent, Cox discloses that the number and location of high-mass links can be varied as the application requires (Col 4, lines 5-14).

5. Cox does not disclose that the special strut extends from a peak at the distal end of the serpentine band to a trough at the proximal end of the serpentine band.

6. Garrison discloses a stent (37, Fig. 1) with a radiopaque marker (42) extending from a peak at the distal end of the serpentine band to a trough at the proximal end of the serpentine band. Garrison also discloses a stent (72, Fig. 2) with a radiopaque marker (79) extending from a peak/trough of one serpentine band to a peak/trough of another serpentine band, just as is disclosed by Cox.

7. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the radiopaque markers onto the struts that extend from a peak to a trough of one serpentine band instead of the radiopaque marker on a strut that extends from one band to an adjacent band. Cox discloses the claimed invention except for the special strut extends from a peak/trough of one serpentine band to a peak/trough of an adjacent serpentine band instead of the special strut extending from a peak at the distal end of the serpentine band to a trough at the proximal end of the serpentine band. Garrison shows that placing the radiopaque marker directly on the struts that extend from a peak to a trough of a serpentine band is a structure that is

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known in the art as an equivalent to placing a radiopaque marker on a connecting strut extending from one serpentine band to another. Therefore, because the two different locations of radiopaque markers were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute the special strut with the radiopaque marker extending from a peak at a distal end of the serpentine band to a trough at the proximal end of the serpentine band for the special strut that extends from a serpentine band to an adjacent serpentine band.

8. Cox in view of Garrison does not disclose a stent with a cover.

9. Erbel discloses an endovascular prosthesis (Fig. 3) or stent (20) comprising at least one cover (25) disposed about at least one section of interconnected serpentine segments, marked at the distal end and proximal end by a plurality of radiopaque markers (35). Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90). The nonporous section (25) or cover is disposed about the circumference of the stent, but does not extend about an entire circumference of the stent and does not cover the entirety of the stent as seen in Fig. 3. The cover extends about the medical device in the region of the special struts. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. Erbel further teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Paras. 70-72).

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10. It would have been obvious to one of ordinary skill in the art to incorporate a cover disposed about the stent in the area of radiopaque markers. Using a cover on the stent enhances the properties of the stent to cause thrombosis at the site of the aneurysm or tear while at the same time allowing blood to flow through the stent and the vasculature. Using radiopaque markers at the edge of the cover facilitates correct placement of the cover at the site of the aneurysm or tear in the body lumen. Erbel provides the motivation. The inventions are analogous with each other and with the instant invention therefore a combination is proper.

11. Claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky (USPN 6,730,116) in view of Burgermeister (USPN 6,790,227) and further in view of Erbel et al. (USpub 2004/0116998).

12. Wolinsky teaches a stent having a longitudinal axis, comprising a plurality of serpentine bands having peaks and troughs and struts extending from a peak to a trough. At least one band includes a special strut (Fig. 3, 28 and Fig. 8, 62a) having a radiopaque marker between first and second regions of curvature. There is a plurality of interconnected struts on either side of the special strut having a complementary shape to the special strut and which curve about the first and second regions. The special struts are in a region between the ends (edges) of the stent. One of the special struts is located in a serpentine band at one end and the other special strut is located in a

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serpentine band at another end of the stent. Wolinsky further teaches, "stents can be used to repair aneurysms" (Col. 1, line 36).

13. Wolinsky does not disclose that the serpentine bands are connected by a connector, which extends from one of the ends of the first band to one of the ends of the second band. Rather, Wolinsky discloses that the connectors extend from the middle of the first band to the middle of the second band.

14. Burgermeister discloses a stent with serpentine bands having peaks and troughs with each band connected to the adjacent band by connectors. In one embodiment the connectors that extend from the distal end of one band to the proximal end of the adjacent band (Fig. 4A; Col 3, lines 14-23; Col 6, line 50 – Col 7, line 40). Burgermeister states that this configuration is advantageous because it provides great flexibility for getting through tortuous vessels and reduces foreshortening. In another embodiment, the connectors extend from the middle of a serpentine band to the middle of the adjacent serpentine band (Fig. 8A, Col 3, lines 38-57; Col 8, line 31 – Col 9, line 28), just as is disclosed by Wolinsky. Burgermeister states that this connector is advantageous because the overall length of the stent is maintained during expansion.

15. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate connecting struts that extend from the distal end of the serpentine band to the proximal end of the adjacent serpentine band into the stent of Wolinsky. Wolinsky discloses the claimed invention except for the connecting struts extend from the middle of the serpentine bands instead of extending from the ends of the serpentine bands. Burgermeister shows that the connecting struts extending from

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the ends of the serpentine bands is an equivalent structure known in the art.

Burgermeister further provides advantages and motivation for both arrangements.

Therefore, because the two types of connectors were art recognized equivalents at the time of the invention was made; one of ordinary skill in the art would have found it obvious to substitute one structure for the other.

16. Wolinsky in view of Burgermeister fails to teach a stent with a cover.

17. Erbel discloses an endovascular prosthesis (Fig. 3) or stent comprising an annular portion with a porous section (20) and a nonporous section (25). As to claims 34-35, the nonporous section (25) or cover is disposed about the circumference of the stent and does not cover the entirety of the stent as seen in Fig. 3. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. Erbel further teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Para70-72). The cover disposed about the stent in a region including radiopaque markers (35). The radiopaque markers designate the proximal and distal ends of the region of the cover. Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90).

18. It would have been obvious to one of ordinary skill in the art to incorporate a cover onto the stent to enhance the capabilities of the stent. Erbel provides the motivation that using a cover on the stent enhances the properties of the stent as it

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could then be used to promote thrombosis at the regions of aneurysms and tears while allowing blood flow through the lumen. He further provides the motivation for using radiopaque markers at the end regions of the cover. The inventions are analogous with each other and with the instant invention therefore a combination is proper.

19. As to Claim 8, 26 and 27, Wolinsky in view of Burgermeister and further in view of Erbel teaches that using radiopaque markers to designate the proximal and distal ends of the region of the cover facilitates correct placement of the stent. However, Wolinsky in view of Erbel does not disclose the size of the cover and therefore does not disclose that the special struts are located on the intermediate bands, anywhere between the middle of the stent and a position one half of the way from the middle of the stent to an end of the stent.

20. It would have been obvious to one having ordinary skill in the art at the time of the invention to alter the size of the cover depending on size of the vessel, the size of the stent and the size of the lesion that it is treating. And therefore the markers could be located at a position one half of the way from the middle of the stent to an end of the stent.

21. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view of Burgermeister and further in view of Erbel as applied to claim 1 above, and further in view of Barone (USPN 6,613,078).

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22. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Garrison and further in view of Erbel as applied to claim 1 above, and further in view of Barone (USPN 6,613,078).

23. Modified Cox and modified Wolinsky teach a stent with a cover marked at the periphery by special radiopaque struts as stated above, but do not teach a second cover.

24. Barone teaches a stent with two covers shown in Fig. 7. The figure shows two stent grafts occluding where the vessel is ruptured but keeping the flow of the blood through the ostium of the vessel branch. Barone states that the use of 2 covers is desirable to repair blood vessels with lesions wherein the wall of the vessel is not in condition to receive and firmly retain an implanted graft (Col 2, lines 20-25 and Col 1, lines 8-17).

25. At the time of the invention it would have been obvious to one of ordinary skill in the art to combine the second cover of Barone into the modified stent of Wolinsky and the modified stent of Cox. Barone provides the motivation in that a stent with two covers enhances the function of the stent since it can be used to repair branched vessels with multiple lesions. The inventions are analogous with each other and the instant invention and so the combination is proper.

26. Claims 13 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Garrison and further in view of Erbel as applied to claim 1 above, and further in view of admitted prior art (admission).

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27. Claims 13 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view of Burgermeister and further in view of Erbel as applied to claim 1 above, and further in view of admitted prior art (admission).

28. Modified Cox and modified Wolinsky disclose the claimed invention as stated above except for the different forms of radiopaque markings.

29. Admission discloses that the radiopacity may be provided by plating, painting, pressing, swaging or welding or "any other suitable means known in the art" (specification page 8, Para 0045). Additionally, Admission discloses, "One of ordinary skill in the art at the time of the invention would recognize that radiopaque markers in the form of plated, coated, painted, swaged or welded radiopaque material have different characteristics." (Remarks, 04/24/06, page 7, Para 4).

30. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the radiopacity by the various forms since it was well known in the art.

Response to Arguments

31. Applicant's arguments filed 09/06/07 have been fully considered but they are not persuasive. Regarding the combination of Cox and Garrison, examiner finds applicant's arguments somewhat confusing. Applicant starts by stating that Garrison's ring (37) in Fig. 1 is not a stent since Garrison refers to it as a ring and therefore it cannot be used for modifying a stent. Applicant then goes on agree that Fig. 2 (ring 71) does disclose "the radiopaque marker extends from a peak/trough of one serpentine band to a peak/trough of another serpentine band". In this statement applicant is admitting that

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this particular ring (71) does meet the structure of a stent with a radiopaque marker located between its bands. Applicant's argument in this case is that this particular structure does not meet the claimed limitations. Respectfully, applicant cannot have it both ways. Either both ring structures (37, 71) are stents or neither is. In addition to applicant admitting that one ring structure meets the stent structure, examiner finds further evidence within the prior art. In light of the fact that applicants may be their own lexicographer, examiner asserts that it is of no significance what label is given to the structure as long as the structure meets the limitations. There are many references within the Garrison reference that imply that the rings have the same structure as the stents: they are made of the same material as the stent, expand with the stent upon delivery, formed from laser cut tubing in same manner as stents and crimped simultaneously as the stent (Col 2, lines 33-49 and Col 3, lines 1-18). It is well within reason to consider the rings as stents and to look to their structure to consider placement of radiopaque markers on stents. Garrison teaches that it is equivalent structure to place radiopaque markers either on the struts or on the connectors. It would have been well within the skill of the ordinary artisan to substitute one known element for another when the results are predictable as evidenced by Garrison.

32. Regarding the combination of Wolinsky and Burgermeister, applicant argues that one would not look to Burgermeister to modify Wolinsky since Wolinsky already incorporates the improvements that Burgermeister provides. It is true that the Wolinsky reference and the Burgermeister reference both address the same issues which are preventing stent foreshortening while maintaining stent flexibility. Burgermeister shows

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that these issues can be addressed by either providing connectors that extend from a peak of one band to a trough of another band, or by providing connectors that extend from the middle of a strut in one band to the middle of a strut in another band.

Burgermeister teaches that both structures are equivalent in the art and provides the benefit in varying the structures. A person of ordinary skill in the art has good reason to pursue the known options within his technical grasp (provided by Burgermeister) in order to solve a recognized problem in the art.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

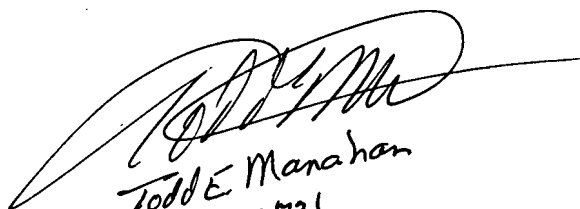
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh



Todd E. Manahan
SPE 3731